



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

3/891d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-01-02W

VIA FEDERAL EXPRESS

October 10, 2001

James Barry
President
Pier Fish Company, Inc.
10 Newmarket Square
Boston, MA 02118

Dear Mr. Barry:

We inspected your firm, located at 10 Newmarket Square, Boston, MA, on September 17 through 19, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were brought to your attention during previous inspections, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, on several occasions, your firm did not record any temperatures at the receiving critical control point, (CCP) to control the pathogen hazard listed in your HACCP plan for shellfish. Also, your firm was missing temperatures, on at least 11 days, at the storage CCP to control the histamine hazard for scombrotoxic species.


We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your modified HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail T. Costello
District Director
New England District Office

Cc:

Kevin B. Barry
Vice President
Pier Fish Company, Inc.
10 Newmarket Square
Boston, MA 02118